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9 UNITED STATES DISTRICT COURT
10 CENTRAL DISTRICT OF CALIFORNIA

11 REGINA FONG AND LORENZO
12 FONG,

13 Plaintiffs,

14 VS.

15 AMERICAN MEDICAL SYSTEMS,
16 INC., AMERICAN MEDICAL
17 SYSTEMS HOLDINGS, INC.; ENDO
PHARMACEUTICALS, INC.; ENDO
PHARMACEUTICALS HOLDINGS,
INC. and DOES 1-40, inclusive,

18 Defendants.

19 Case No. 2:18-cv-09914-VAP-JC

DISCOVERY MATTER

**AMENDED CONFIDENTIALITY
AND PROTECTIVE ORDER**

1 WHEREAS, Plaintiffs Regina Fong and Lorenzo Fong (“Plaintiff” or
2 “Plaintiffs”), and Defendants Astora Women’s Health, LLC (f/k/a American Medical
3 Systems, Inc.), American Medical Systems Holdings, Inc., Endo Pharmaceuticals Inc.,
4 and Endo Health Solutions Inc. (f/k/a Endo Pharmaceuticals Holdings Inc.)
5 (collectively, “Defendants”) jointly believe that entry of a protective order pursuant to
6 Federal Rule of Civil Procedure 26(c) should be applied to this matter;

7 WHEREAS, a protective order will expedite the flow of discovery material,
8 facilitate the prompt resolution of disputes over confidentiality, and adequately protect
9 confidential material;

10 NOW, THEREFORE, having found good cause, it is hereby ORDERED
11 THAT:

12 **I. Scope of Order**

13 Disclosure and discovery in this proceeding may involve production of
14 information and/or materials which are claimed to include confidential, proprietary, and
15 private information for which special protection from public disclosure and from any
16 purpose other than prosecuting this litigation may be warranted. Accordingly, the
17 parties hereby stipulate to and petition the court to enter their Stipulated Confidentiality
18 and Protective Order (the “Order”) in this matter. This Order applies equally to
19 CONFIDENTIAL and HIGHLY CONFIDENTIAL material (as defined below)
20 produced/provided and designated as such in this action.

21 **II. Good Cause Statement**

22 This action is likely to involve trade secrets, commercial, financial, and/or
23 proprietary information for which special protection from public disclosure and from
24 use for any purpose other than prosecution of this action is warranted. Such confidential
25 and proprietary materials and information consist of, among other things, confidential
26 business or financial information, information regarding confidential business practices,
27 or other confidential research, development, or commercial information (including
28 information implicating privacy rights of third parties), information otherwise generally

1 unavailable to the public, or which may be privileged or otherwise protected from
2 disclosure under state or federal statutes, court rules, case decisions, or common law.
3 Accordingly, to expedite the flow of information, to facilitate the prompt resolution of
4 disputes over confidentiality of discovery materials, to adequately protect information
5 the parties are entitled to keep confidential, to ensure that the parties are permitted
6 reasonable necessary uses of such material in preparation for and in the conduct of trial,
7 to address their handling at the end of the litigation, and serve the ends of justice, a
8 protective order for such information is justified in this matter. It is the intent of the
9 parties that information will not be designated as confidential for tactical reasons and
10 that nothing be so designated without a good faith belief that it has been maintained in
11 a confidential, non-public manner, and there is good cause why it should not be part of
12 the public record of this case.

13 **III. The Order**

14 **A. Stipulation**

15 1. By stipulating to the Order, the parties have agreed to be bound by its terms
16 and to request its entry by the Court.

17 **B. Discovery Phase**

18 1. For purposes of this Order, the following definitions shall apply: (a) the
19 term “document” and “electronically stored information” shall have the full meanings
20 ascribed to each by the Federal Rules of Civil Procedure and the United States District
21 Court for the Central District of California Local Rules (“Local Rules”), and relevant
22 case law; and (b) the term “producing party” shall be defined as any party or non-party
23 who is required to produce or provide materials or testimony containing confidential
24 information.

25 2. A producing party may designate as “CONFIDENTIAL” any material the
26 producing party believes in good faith constitutes or discloses information that qualifies
27 for protection, including but not limited to, deposition and trial testimony/transcripts
28 and exhibits thereto, and specifically information that is trade secret or other

1 confidential research, development, or commercial information, and materials that are
2 deemed confidential under Federal Drug Administration (“FDA”) regulations and
3 Health Insurance Portability and Accountability Act (“HIPAA”) statutes and/or
4 regulations.

5 3. Confidential information may be further designated as “**HIGHLY**
6 **CONFIDENTIAL**” if a Defendant produces materials, including but not limited to,
7 deposition and trial testimony/transcripts and exhibits thereto, that it believes in good
8 faith would, if disclosed, cause substantial economic harm to the competitive position
9 of the entity from which the information was obtained because it is **HIGHLY**
10 **CONFIDENTIAL** research and development material on a new product that has not
11 been approved or cleared by the FDA or a similar regulatory body or reflects a party’s
12 price competitiveness in the market or marketing business strategies of a party
13 concerning a current or new product. Counsel will inform the producing party of its
14 intent to disclose such information to any individual who is currently, or who at any
15 time during the pendency of this litigation becomes, a consultant to a competitor of the
16 producing party in the pelvic organ mesh business, or is a consultant to an entity actively
17 investigating entering such business, and thereafter will follow the procedures for
18 disclosure of such materials to such individual as provided in Paragraph III.B.8 of this
19 Order.

20 4. Challenges to Designations or Redacted Information: Any party may at
21 any time that is consistent with the District Judge’s scheduling orders challenge the
22 redaction or the designation of information as **CONFIDENTIAL** or **HIGHLY**
23 **CONFIDENTIAL** by providing written notice of its objection to the designating party,
24 or, in the case of a deposition, either on the record at a deposition or in writing later.
25 Thereafter, counsel for the objecting party must arrange for a meet and confer
26 conference consistent with Local Rule 37-1. If, after the meet-and-confer process
27 required by Local Rule 37-1, the parties cannot reach an agreement, the party claiming
28 the designation of confidentiality or redaction may apply for an appropriate ruling from

1 the Court by following Local Rule 37-2 procedure for Moving Papers, including the
2 filing of a Joint Stipulation, and noticing the hearing of the motion in accordance with
3 Local Rule 37-3. The disputed material shall continue to be treated as designated, or
4 redacted, until the Court orders otherwise. In any such application concerning a ruling
5 on confidentiality or redacted information, the party claiming the designation of
6 confidentiality or redaction has the burden of establishing that such confidential
7 designation or redaction is proper.

8 5. No person or party subject to this Order shall distribute, transmit, or
9 otherwise divulge any material marked **CONFIDENTIAL** or **HIGHLY**
10 **CONFIDENTIAL**, except in accordance with this Order.

11 6. Use of Confidential Material Limited to this Action: Any document or
12 other material which is marked **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL**,
13 or the contents thereof, may be used by a party, or a party's attorney (inside counsel or
14 outside counsel), expert witness, consultant, or other person to whom disclosure is
15 made, only for the purpose of this action. Nothing contained in this Order shall prevent
16 the use of any document or the contents thereof, at any deposition taken in this action.
17 If a party intends to use material that has been marked as **HIGHLY CONFIDENTIAL**
18 at the deposition of an employee or former employee of a non-producing party in this
19 litigation, then the party shall notify the producing party ten (10) days in advance of the
20 deposition that it intends to use that category of material. If the parties cannot agree on
21 parameters for usage of the material at the deposition, then the producing party will seek
22 the direction of the Court as to the utilization of that category of material in the
23 deposition, in accordance with the District Judge's scheduling orders and Local Rules.

24 7. Access to Confidential Material: If a party or attorney wishes to disclose
25 any document or other material which is marked **CONFIDENTIAL** or **HIGHLY**
26 **CONFIDENTIAL**, or the contents thereof, to any person actively, or retained to, work
27 on this action (e.g., expert witness, consultant), the person making the disclosure shall
28 do the following:

- (a) Provide a copy of this Order to the person to whom disclosure is made;
- (b) Inform the person to whom disclosure is made that s/he is bound by this Order;
- (c) Require the person to whom disclosure is made to sign an acknowledgment and receipt of this Order;
- (d) Instruct the person to whom disclosure is made to return or, in the alternative and with permission of the producing party, at the conclusion of the case to destroy any document or other material which is marked **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL**, including notes or memoranda made from **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL** material;
- (e) Maintain a list of persons to whom disclosure was made and the **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL** materials which were disclosed to that person;
- (f) At the conclusion of this action, gather the **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL** materials, copies thereof, and related notes and memoranda, and return them to the party or attorney who originally disclosed them, or destroy them, providing a certificate of compliance with the terms of this Protective Order. If counsel for one party have created work product incorporating, describing or referring to another party's confidential or highly confidential documents, counsel who have created the work product must collect all copies from experts and other consultants and must return or destroy all copies of confidential or highly confidential documents attached to the work product. However, the counsel that created the work product may retain the work product itself once all copies are collected and all copies of confidential or highly confidential documents are returned or destroyed. No work product incorporating, describing or referring to another party's confidential or highly confidential documents

1 may be disseminated to any person or used for any purpose once the
2 litigation is concluded.; and

3 (g) With respect to access or use of **HIGHLY CONFIDENTIAL** documents
4 by in-house counsel, only “Designated In-House Counsel” of Defendants
5 may have access to information designated as **HIGHLY**
6 **CONFIDENTIAL** by another producing party. “Designated In-House
7 Counsel” shall mean: (1) an in-house attorney; and (2) one paralegal and/or
8 clerical employee for each such Designated In-House Counsel to provide
9 administrative support. Each Designated In-House Counsel shall complete
10 and sign a copy of the Undertaking in Exhibit A, and each such completed,
11 signed form shall be transmitted by e-mail to counsel for the other parties
12 before disclosure of any such other party’s **CONFIDENTIAL** or
13 **HIGHLY CONFIDENTIAL** information to the Designated In-House
14 Counsel.

15 8. Disclosure Requirements for **HIGHLY CONFIDENTIAL** information to
16 Competitor Related Consultants: Prior to disclosure, plaintiff(s) will inform the
17 producing party of its intent to disclose **HIGHLY CONFIDENTIAL** material to
18 anyone who is currently, or who at any time during the pendency of this litigation
19 becomes, a consultant to a competitor (as such individuals are defined in Paragraph
20 III.B.3 above) in the manner set forth below:

21 (a) Give at least ten (10) day notice in writing to counsel for the party who
22 designated such information as **HIGHLY CONFIDENTIAL** of the intent
23 to so disclose that information, although the disclosing party is not required
24 to identify the intended recipient of such materials.

25 (b) Within ten (10) days thereafter, counsel for the parties shall attempt to
26 resolve any disputes between them regarding the production of the
27 **HIGHLY CONFIDENTIAL** material to the intended individuals, in
28 accordance with Local Rule 37-1.

- (c) If the parties are unable to resolve any dispute regarding such production, within an additional seven (7) days, the party who designated the information in question as **HIGHLY CONFIDENTIAL** shall file a motion objecting to the proposed disclosure by following Local Rule 37-2 procedure for Moving Papers, including the filing of a Joint Stipulation, and noticing the hearing of the motion in accordance with Local Rule 37-3. In making such motion, it shall be the producing party's burden to demonstrate good cause for preventing the disclosure.
- (d) If the Court permits disclosure of the material designated as **HIGHLY CONFIDENTIAL** at issue, the information remains designated as **HIGHLY CONFIDENTIAL** and the individual receiving such information shall be bound by the requirements of Paragraph III.B.7.

13 9. Redaction of CONFIDENTIAL Material: The parties recognize that
14 certain FDA, other governmental agencies, and certain relevant statutes require
15 redaction of certain information prior to production of certain information by
16 Defendants and that Defendants will comply with those requirements and redact such
17 information as directed. Producing parties will provide a redaction log identifying the
18 reason for redaction. Any party challenging information that has been redacted may do
19 so in accordance with Paragraph III.B.4 of this Protective Order, or otherwise in
20 accordance with the Federal Rules of Civil Procedure and the United States District
21 Court for the Central District of California Local Rules and/or Orders of this Court.

22 10. Use of CONFIDENTIAL Material at Depositions: All transcripts and
23 exhibits shall be treated as if designated **CONFIDENTIAL** for a period of thirty (30)
24 days after the transcript is available from the court reporter. Counsel for any party may
25 designate during the deposition or during the thirty day period after the transcript is
26 available from the court reporter any portion of the transcript as **CONFIDENTIAL** or
27 **HIGHLY CONFIDENTIAL** by denominating by page and line, and by designating
28 any exhibits, that are to be considered **CONFIDENTIAL** or **HIGHLY**

1 **CONFIDENTIAL** pursuant to the criteria set forth in this Order. Such designation shall
2 be communicated to all parties. Transcript portions and exhibits designated in
3 accordance with this paragraph shall be disclosed only in accordance with this Order.
4 A party may challenge the **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL**
5 designation or portions thereof in accordance with the provisions of Paragraph III.B.4
6 above.

7 11. Inadvertent Failure to Properly Designate **CONFIDENTIAL** Material:
8 Inadvertent production of any document or information without a designation of
9 **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL** will not be deemed to waive a
10 party's claim to its **CONFIDENTIAL** nature or stop said party from designating said
11 document or information as **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL** at a
12 later date. Disclosure of said document or information by another party prior to such
13 later designation shall not be deemed a violation of the provisions of this Order.

14 12. Inadvertent Disclosure of Privileged Documents, "Clawback" Procedure:
15 Inadvertent production of documents or electronically stored information ("ESI")
16 (collectively "Inadvertently Produced Documents") subject to work-product or
17 attorney-client privilege, or other legal privilege protecting information from discovery,
18 shall not constitute a waiver of the privilege, provided that the producing party shall
19 notify the receiving party in writing as set forth herein. In the event that a party
20 inadvertently produces documents or ESI subject to a claim of privilege, the producing
21 party shall, within ten (10) days of the discovery of the inadvertent disclosure, notify
22 the other party in writing of the inadvertent disclosure. The producing party may, in the
23 notice, request a "clawback" of the inadvertently disclosed material. The party receiving
24 such clawback notice shall immediately and diligently act to retrieve the Inadvertently
25 Produced Documents, and all copies, including any loaded to databases, and return them
26 to the producing party or destroy them as agreed between the parties. All notes or other
27 work product of the receiving party reflecting the contents of such materials shall be
28 destroyed and not used.

If the receiving party elects to file a motion as set forth below, the receiving party, subject to the requirements below, may retain possession of the Inadvertently Produced Documents as well as any notes or other work product of the receiving party reflecting the contents of such materials pending the resolution by the Court of the motion below, but shall segregate and not use them pending resolution of the motion. If the receiving party's motion is denied, the receiving party shall promptly comply with the immediately preceding provisions of this paragraph. No use shall be made of such Inadvertently Produced Documents during depositions or at trial, nor shall they be disclosed to anyone who was not given access to them prior to the request to return or destroy them unless otherwise ordered by the Court.

The party receiving such Inadvertently Produced Documents may, after receipt of the producing party's notice of inadvertent production, move the Court to dispute the claim of privilege, in accordance with the District Judge's scheduling orders and Local Rules.

13. There is no waiver of privilege or work product protection in this matter or any other matter in any other jurisdiction for any document clawed-back under this clause, or for the subject matter of any such document, whether the privileged document was inadvertently provided following review or as part of a "Quick Peek" production. In the event that any party receives information produced in discovery from any other party that reasonably appears to be Inadvertently Produced Documents, the receiving party shall promptly notify the producing party in writing of the apparent inadvertent production.

14. **Disclosure/Production of Documents, No Waiver:** A party's disclosure or production of any document or group or category of documents (the "produced documents") shall not constitute a waiver of any privilege or protection, including but not limited to privilege or work product protection with respect to: (a) any other communications or documents relating or referring to the same or similar subject matter ("subject matter waiver"); and (b) any other communications or documents referring or

1 relating to the parties who sent or received or are named in any such document or
2 documents. A party thus may not challenge another party's claims of privilege for
3 documents remaining on its privilege logs on grounds of waiver of any privilege or
4 protection.

5 **C. POST DISCOVERY PHASE**

6 1. If any party or attorney wishes to file, or use as an exhibit or as testimonial
7 evidence at a hearing or trial, any **CONFIDENTIAL** or **HIGHLY CONFIDENTIAL**
8 material, such party must provide reasonable notice to the producing party of the
9 intended use of such information. The parties shall then attempt to resolve the matter of
10 continued confidentiality by either (a) removing the **CONFIDENTIAL** or **HIGHLY**
11 **CONFIDENTIAL** marking, (b) creating a mutually acceptable redacted version that
12 suffices for purposes of the case, or (c) conferring about methods to avoid or limit public
13 disclosure of such information during testimony. If an amicable resolution proves
14 unsuccessful, the proponent of continued confidentiality may present the issue to the
15 Court for resolution. The proponent of continued confidentiality will have the burden
16 of persuasion that the document or material should be withheld from the public record.

17 2. Survival of Protective Order: Throughout and after the conclusion of this
18 litigation, including any appeals, the restrictions on communication and disclosure
19 provided for herein shall continue to be binding upon the parties and all other persons
20 to whom **CONFIDENTIAL** and **HIGHLY CONFIDENTIAL** material has been
21 communicated or disclosed pursuant to the provisions of this Order or any other order
22 of the Court.

23 3. Return or Destruction of **CONFIDENTIAL** Material Upon Termination
24 of Litigation: Within sixty (60) days after the final termination of this action, each party,
25 upon request of the other party, shall either return to the producing party, or destroy, all
26 **CONFIDENTIAL** and **HIGHLY CONFIDENTIAL** material designated by any other
27 party (including any such material disclosed to third persons), except for any attorneys'

1 work-product for the party returning the material, and shall provide confirmation in
2 writing to opposing counsel if such materials are destroyed.

3 4. Modification of this Order: Nothing in this Order shall prevent any other
4 party from seeking amendments broadening or restricting the rights of access to or the
5 use of **CONFIDENTIAL** and/or **HIGHLY CONFIDENTIAL** material or otherwise
6 modifying this Order; and this Order may be amended without leave of the Court by the
7 agreement of the undersigned attorneys for the parties in the form of a Stipulation that
8 shall be filed in this case.

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IT IS SO ORDERED on this 26th day of June, 2019.

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/s/

Honorable Jacqueline Chooljian
United States Magistrate Judge

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EXHIBIT A

ACKNOWLEDGMENT AND AGREEMENT TO BE BOUND

I, _____ [print or type full name], of _____ [print or type full address], declare under penalty of perjury that I have read in its entirety and understand the Amended Confidentiality and Protective Order that was issued by the United States District Court for the Central District of California on June 26, 2019 in the case of *Regina Fong, et al. v. American Medical Systems, Inc., et al.*, United States District Court, Central District of California, Case No. 2:18-cv-09914-VAP-JC. I agree to comply with and to be bound by all the terms of the Amended Confidentiality and Protective Order and I understand and acknowledge that failure to so comply could expose me to sanctions and punishment in the nature of contempt. I solemnly promise that I will not disclose in any manner any information or item that is subject to the Amended Confidentiality and Protective Order to any person or entity except in strict compliance with the provisions of such Order. I further agree to submit to the jurisdiction of the United States District Court for the Central District of California for enforcing the terms of this Amended Confidentiality and Protective Order, even if such enforcement proceedings occur after termination of this action. I hereby appoint _____ [print or type full name] of _____ [print or type full address and telephone number] as my California agent for service of process in connection with this action or any proceedings related to enforcement of the Amended Confidentiality and Protective Order.

24 Date: _____

25 | City and State where sworn and signed: _____

26 Printed name: _____

27 | Signature: _____